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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,994

01/31/2007

Betty A. Diamond

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3486

1912

7590

08/26/2010

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EXAMINER

NIEBAUER, RONALD T

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

08/26/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 10/574,994	<b>Applicant(s)</b> DIAMOND ET AL.	
	<b>Examiner</b> RONALD T. NIEBAUER	<b>Art Unit</b> 1654	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 20 August 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): 112 2<sup>nd</sup> rejection of claim 51.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 23,25,45-48,51 and 55-57.  
 Claim(s) withdrawn from consideration: 54.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

/Cecilia Tsang/  
 Supervisory Patent Examiner, Art Unit 1654

Continuation of 11. does NOT place the application in condition for allowance because: With respect to the 103 rejection applicants argue that Gaynor does not teach treating cognitive dysfunction or lupus-induced cognitive dysfunction.

Applicants argue that although DeGiorgio teach that 'up to 80% of lupus patients experience CNS disease characterized by neuropsychiatric symptoms and cognitive decline' that such does not render obvious the instant claims.

Applicants argue that the instant invention recognizes a need for determining the cause of cognitive dysfunction.

Applicant's arguments filed 8/20/10 have been fully considered but they are not persuasive.

Claims 23,25,45-48,51,55-57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gaynor et al (US 6,001,964 as cited in IDS 2/19/09) and Degiorgio et al (Nature Medicine 'A subset of lupus anti-DNA antibodies cross-reacts with the NR2 glutamate receptor in systemic lupus erythematosus' 2001 v30 pages 1189-93 as cited in IDS 1/31/07).

Although applicants argue that Gaynor does not teach treating cognitive dysfunction or lupus-induced cognitive dysfunction, it is noted that the instant rejection is a multiple reference 103 rejection and as such any single reference does not necessarily anticipate the claims.

Further, it is noted that claim 23 refers to 'being at risk for lupus-induced cognitive dysfunction'. One who is at risk for lupus-induced cognitive dysfunction does not necessarily have lupus-induced cognitive dysfunction.

Although Applicants argue that although DeGiorgio teach that 'up to 80% of lupus patients experience CNS disease characterized by neuropsychiatric symptoms and cognitive decline' that such does not render obvious the instant claims, since Gaynor teach a method for treating systemic lupus erythematosus in a subject in need of such treatment one would be motivated to treat such patients. Thus one would be motivated to patients with lupus. It is noted that such patients (patients with lupus) are at risk for lupus-induced cognitive dysfunction since as the name implies it is induced by lupus. Further, since Degiorgio teach that up to 80% of lupus patients experience symptoms including cognitive decline (page 1189 first paragraph) one would be motivated to treat those with lupus who have cognitive decline. In other words, by stating 'up to 80% of lupus patients experience symptoms including cognitive decline' Degiorgio suggests a specific patient population.

Although Applicants argue that the instant invention recognizes a need for determining the cause of cognitive dysfunction, it is noted that such information is not recited in the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Thus, Claims 23,25,45-48,51,55-57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gaynor et al (US 6,001,964 as cited in IDS 2/19/09) and Degiorgio et al (Nature Medicine 'A subset of lupus anti-DNA antibodies cross-reacts with the NR2 glutamate receptor in systemic lupus erythematosus' 2001 v30 pages 1189-93 as cited in IDS 1/31/07).